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Application No.	Ref.	Date
04 772 194.9 - 2405	M1335 EP S3	29.07.2008
Applicant TAKARA BIO INC.		

Communication pursuant to Article 94(3) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(2) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 126(2) and 131(2) and (4) EPC. One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (R. 50(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Art. 94(4) EPC).

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Obel, Nicolai
Primary Examiner
For the Examining Division

Enclosure(s): 2 page/s reasons (Form 2906)

The examination is being carried out on the **following application documents**:

Description, Pages

1-189 as originally filed

Sequence listings, Pages

1-46 as originally filed

Claims, Numbers

1-17 received on 09.06.2008 with letter of 06.06.2008

Drawings, Sheets

1 as originally filed

1. The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claims 1,3-10,15 is not new within the meaning of Article 54(1) and (2) EPC.

1.1 The novelty objection raised in the previous communication of 15.11.2007 is maintained. The arguments brought forward by the applicant regarding D6 are correct in so far the claims were limited to a method for expanding a precursor cell which can be formed into a cytotoxic lymphocyte. This is however not clear from the claim as the claim states "expansion of cytotoxic lymphocytes from ...". This formulation fails to make clear that the expansion is with regard to the precursor cell. The claim in its present form is directed to expansion with regard to cytotoxic lymphocytes and said

cells are merely derived from a precursor, i.e all cells.

1.2 The novelty and inventive step is further compromised by the formulation regarding the serum concentration. Claim 1 and 15 state "a total concentration of 0% by volume or more and less than 3%". The applicant regards this as meaning between 0% and 3% by volume. However, the claim can also be understood as "0%" or "more and less than 3%" thus describing not a range but two endpoints. A reference to "more and less than 3%" is to be regarded as encompassing the 5% disclosed in the prior art.

1.3 In so far the clarity objections above are resolved, the claims 1-14,16 and 17 can be regarded as new and inventive since example 12 documents as surprising effect of fibronectin, i.e an ability to compensate the lowering of the serum concentration and thus maintain a high expansion rate. This inventive step can be acknowledged for serum concentrations between 0 and 3%.

1.4 Claim 15 is directed to a medium suitable for culturing cytotoxic lymphocytes. Such a medium can be for expansion, maintenance or activation of the lymphocytes. As the prior art discloses such media with 0 and 5% serum, see communication of 20.02.2007 point 2.1, the subject matter is not new in the sense of Article 54 (1) and (2) EPC, see also GL CIII 4.13.

2. With regard to inventive step, please see 1.3

3. The application does not meet the requirements of Article 84 EPC, because claims 1 and 15 are not clear, please see 1.1 and 1.2.

4. When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims. Care should be taken during revision, especially of the introductory portion and of any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).